contain the information allowed for health professionals for antacids and antiflatulents.

[39 FR 19874, June 4, 1974. Redesignated and amended at 55 FR 19859, May 11, 1990]

EFFECTIVE DATE NOTE: At 61 FR 4823, Feb. 8, 1996, in § 331.80, paragraph (a)(1) was revised, effective February 10, 1997. For the convenience of the reader, the revised text is set forth below.

§ 331.80 Professional labeling.

(a) * * *

(1) Shall contain the neutralizing capacity of the product as calculated using the procedure set forth in United States Pharmacopeia 23/National Formulary 18 expressed in terms of the dosage recommended per minimum time interval or, if the labeling recommends more than one dosage, in terms of the minimum dosage recommended per minimum time interval.

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PART 332—ANTIFLATULENT PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

Subpart B—Active Ingredients

Subpart C—[Reserved]

Subpart D—Labeling

AUTHORITY: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

SOURCE: 39 FR 19877, June 4, 1974, unless otherwise noted.

Subpart A—General Provisions

§ 332.1 Scope.

An over-the-counter antiflatulent product in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each of the following conditions and each of the general conditions established in § 330.1 of this chapter.

§ 332.3 Definitions.

As used in this part:

Antigas. A term that may be used interchangeably with the term antiflatulent. Neither term should be considered as describing the mechanism of action of the active ingredient contained in the product.

[61 FR 8838, Mar. 5, 1996]

EFFECTIVE DATE NOTE: At 61 FR 8838, Mar. 5, 1996, § 332.3 was added, effective March 5, 1997.

Subpart B—Active Ingredients

§ 332.10 Antiflatulent active ingredients.

Simethicone; maximum daily dose 500 mg. There is no dosage limitation at this time for professional labeling.

§ 332.15 Combination with non-antiflatulent active ingredients.

An antiflatulent may contain any generally recognized as safe and effective antacid ingredient(s) if it is indicated for use solely for the concurrent symptoms of gas associated with heartburn, sour stomach or acid indigestion.

Subpart C—[Reserved]

Subpart D—Labeling

EFFECTIVE DATE NOTE: At 61 FR 8838, Mar. 5, 1996, subpart D, consisting of §§ 332.30 and 332.31, was redesignated as subpart C, effective March 5, 1997.

§ 332.30 Labeling of antiflatulent products.

(a) *Indications.* The labeling of the product states, under the heading ''Indications,'' the following: ''antiflatulent'' and/or ''to alleviate or relieve the symptoms of gas.'' Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph (a), may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the act relating to